



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,528	07/08/2003	Raymond E. Ideker	5656-31	8193
20792	7590	08/15/2006	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			REIDEL, JESSICA L	
PO BOX 37428				
RALEIGH, NC 27627			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/615,528	IDEKER, RAYMOND E.
	Examiner	Art Unit
	Jessica L. Reidel	3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 08 June 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19-36,55-72 and 91-107 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) 21,36,55-58,60,61,72,96-100,102-107 and 9194 is/are allowed.
 6) Claim(s) 19,20,22-32 and 62-67 is/are rejected.
 7) Claim(s) 33-35,59,68-71,95 and 101 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 08 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06/08/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Acknowledgment is made of Applicant's Amendment, which was received by the Office on June 8, 2006. Claims 1-18, 37-54 and 73-90 have been cancelled. Claims 19-36, 55-72 and 91-107 are pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on June 8, 2006 has been acknowledged and is being considered by the Examiner.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the steps of the method where the fastest activating region is "determined by inducing fibrillation of the heart" and "determining at least one of a monophasic activation potential (MAP) reading associated with the fibrillating heart, a refractory period associated with the heart using premature stimulation, and a power spectrum analysis to provide a spectrum with a peak power at a highest frequency". must be shown or the feature(s) canceled from the claim(s). The "means for inducing fibrillation" must be shown of the feature(s) canceled from the claim(s). Also, the "means for" accomplishing all three of the tasks (see above in this paragraph) after inducing fibrillation must be shown of the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 24, 30, 34, 59, 65, 70, 95 and 101 are objected to because of the following informalities: minor typographical errors rendering the language of these claims awkward.

As to Claims 24, 30, 59, 65, 95 and 101, the Examiner suggests revising the claims to read something similar to, “wherein the reentrant region is characterized by a closed pathway of the tissue of the heart” in order to avoid positively reciting a part of the body. As to Claim 70, the Examiner suggests adding “means for” at the beginning of the second line of the claim in order to add a structural limitation to this claim. As to Claim 34, it appears that this claim should

depend from Claim 27, not Claim 28 and the Examiner is prosecuting the application as if the appropriate changes have been made.

Appropriate correction is required.

Response to Arguments

5. Applicant's arguments with respect to claims 19-20, 22-35, 55, 57-70 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 19-20, 27 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (U.S. 5,865,838) (herein Obel). As to Claims 19-20 and 27, Obel discloses a method for terminating atrial fibrillation comprising detecting atrial fibrillation and applying an electric stimulus to a region of the heart that is determined to contain a fastest activating region (see Obel Abstract). The Examiner takes the position that phrase “atrial fibrillation” encompasses both meanings of “premature heartbeat activity” and “nonsustained tachycardia” since it is well known that a heart that is fibrillating is beating excessively fast and in chaos. It is inherent that a fibrillating heart beats prematurely and has a very fast rhythm that may come and go – i.e. tachycardia that is nonsustained. Obel specifies that determining where to apply the electrical

stimulus comprises measuring waveforms at each of the electrodes that are implanted on or within a patient's heart and the electrode from which a waveform is measured which has the shortest cycle length (i.e. has a fastest activating) is used as the electrode to emit a first pacing pulse, or a series of pacing pulses (see Obel columns 2-4). Although, Obel specifies that the method is for "terminating atrial fibrillation", the Examiner takes the position that Obel is inherently capable of reducing an occurrence of fibrillation of a heart since the method of Obel is practiced following the same steps as Applicant.

8. As to Claims 62, in addition to the arguments presented above, Obel discloses a system comprising means for detecting (via pace and sense channels, electrodes and microprocessor) a premature contraction of a heart for a plurality of beats characterized by nonsustained tachycardia and means for applying an electrical stimulus (i.e. pacing pulse) to a region of a heart determined to contain a fastest activating region (see Obel Fig. 3). The Examiner notes that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the system of Obel is capable of reducing an occurrence of fibrillation of a heart.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 22-26, 28-32 and 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Obel in view of Huang et al. (*Regional Differences in Ventricular Fibrillation in the Open-Chest Porcine Left Ventricle*. Circ. Res. 2002; 733-740) (herein Huang). As to Claims 22, 28 and 63, Applicant differs from Obel in that the fastest activating region comprises a reentrant region having a refractory period that is less than areas adjacent to the reentrant region. The Examiner takes the position that the fastest activating region determined by Obel inherently comprises a reentrant region having a refractory period that is less than areas adjacent to the reentrant region since this is a well-known physiological characteristic of fibrillation mechanisms of the heart with Huang being one example. Huang specifically teaches that a fastest activating region contains a stable reentrant circuit called a mother rotor, which has a shorter refractory period than the remainder epicardial tissue (see Huang page 733).

11. As to Claims 24, 30 and 65, the Examiner takes the position that a reentrant circuit is synonymous with a closed pathway on the heart since the definition of “circuit” is a closed pathway.

12. As to Claims 25-26, 31-32 and 66-67, the Examiner takes the position that a “mother rotor” as well known in the art is synonymous with a wave front that propagates along a reentrant circuit (i.e. closed pathway) from a starting point to an ending point that are adjacent to each other as in a circle or reentrant loop.

13. As to Claims 23, 29 and 64, Applicant differs from Obel in that a first wave front propagates along a closed pathway on the fibrillating heart where the first wave front generates at least a second wave front that propagates on the fibrillating heart outside the fastest activation

region. The Examiner takes the position that a mother rotor is synonymous with a fastest activating region's first wave front. The Examiner also takes the position that mother rotors spawn daughter rotors, which is a well-known physiological characteristic of fibrillation mechanisms of the heart with Huang being one example. Huang specifically teaches that a mother rotor spawns wavefronts that propagate to maintain ventricular fibrillation elsewhere or other than the location of the fastest activating region's mother rotor (see Huang pages 733-740).

Allowable Subject Matter

14. Claims 21, 36, 55-58, 60-61, 72, 9194, 96-100 and 102-107 are allowed.
15. Claims 33-35 and 68-71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
16. Claims 59, 95 and 101 would be allowable if rewritten to overcome the Claim Objections, set forth in this Office Action.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.
18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel
Jessica L. Reidel 08-08-06
Examiner
Art Unit 3766

Robert E. Pezzuto
Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766